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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,738	03/04/2002	Atsushi Miyawaki	P22042	2194

7055 7590 03/15/2004

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,738

Applicant(s)

MIYAWAKI ET AL.

Examiner

Elizabeth Slobodyansky, PhD

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

DETAILED ACTION

The preliminary amendment filed February 13, 2003 amending claim 21 has been entered.

The status request filed February 12, 2004 has been received.

Claims 1-21 are pending.

The examiner notes that the claims refer to SEQ ID NOs:1, 2, 3 as both an amino acid and a nucleotide sequence while the current Sequence Listing filed July 12, 2002 lists them as nucleotide sequences.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 (in part), drawn to a fusion protein comprising a fluorescent protein and a calcium binding protein, classified in class 530, subclass 350.
- II. Claims 5 and 11 (in part, SEQ ID NO: 1), drawn to a fluorescent protein of SEQ ID NO: 1 and a fusion protein comprising thereof, classified in class 530, subclass 350.
- III. Claims 5 and 11 (in part, SEQ ID NO: 2), drawn to a fluorescent protein of SEQ ID NO: 2 and a fusion protein comprising thereof, classified in class 530, subclass 350.

- IV. Claims 5 and 11 (in part, SEQ ID NO: 3), drawn to a fluorescent protein of SEQ ID NO: 3 and a fusion protein comprising thereof, classified in class 530, subclass 350.
- V. Claims 6-10 and 12, drawn to a fused fluorescent protein and a calcium ion indicator comprising thereof, classified in class 530, subclass 350.
- VI. Claim 13, drawn to a method of use of a protein of claim 6, classified in class 435, subclass 4.
- VII. Claims 14, 18 and 19, drawn to a DNA encoding the fluorescent protein of claim 1, a vector and a transformant comprising thereof, classified in class 435, subclass 252.3.
- VIII. Claims 15 and 17 (in part, SEQ ID NO:1), drawn to a DNA encoding a fluorescent protein of SEQ ID NO:1 and a variant thereof, classified in class 536, subclass 23.5.
- IX. Claims 15 and 17 (in part, SEQ ID NO:2), drawn to a DNA encoding a fluorescent protein of SEQ ID NO:2 and a variant thereof, classified in class 536, subclass 23.5.
- X. Claims 15 and 17 (in part, SEQ ID NO: 3), drawn to a DNA encoding a fluorescent protein of SEQ ID NO: 3 and a variant thereof, classified in class 536, subclass 23.5.
- XI. Claim 16, drawn to a DNA encoding a fluorescent protein of claim 6, classified in class 536, subclass 23.4.

XII. Claim 20, drawn to a method of use a transformant of claim 19, classified in class 435, subclass 4.

XIII. Claim 21, drawn to a kit comprising a fluorescent fusion protein, classified in class 435, subclass 810.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V, VII-XI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the different inventions, represent structurally different fluorescent proteins or florescent fusion proteins and the polynucleotides encoding them. Therefore, where structural identity is required, such as for fluorescent effects, the different sequences have different effects.

Inventions I-V, XIII and VII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to divergent molecules having different functions and effects. The polynucleotides can be used in hybridization assays as well as in expression methods for producing the polypeptides. The polypeptides can be used to monitor different cell events.

Inventions (V and VI) and (VII and XII), respectively, are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be use in various assays and the polynucleotide can be used in a materially different process such as one in which the polynucleotide is used to transform a host cell for heterologous expression of the polypeptide. The methods of inventions VI and XII are patentably distinct as drawn to methods of use of different compounds such as a polypeptide and a DNA.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Mr. Bruce Bernstein on March 9, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for

patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "E. Slobodyansky". The signature is fluid and cursive, with the first letter "E" being large and stylized.

Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

March 9, 2004